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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,636	03/24/2004	Jun Feng	DPP-IV-5004-CI	7481
32793	7590	09/01/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			HABTE, KAHSAY	
			ART UNIT	PAPER NUMBER

.1624

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/809,636	Applicant(s) FENG ET AL.	
	Examiner Kahsay Habte	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33,36,42,43,55-61,87,88,95,99,100 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 34,35,37-41,44-54,62-86,89-94,96-98,101,102 and 104-114.

DETAILED ACTION

1. Claims 1-114 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 8/16/2006 in response to the previous Office Action (4/27/2006) is acknowledged. Rejections of claims 1-10, 15-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 under 35 U.S.C. § 112, second paragraph (items 6a-6e) and the double patenting rejection (items 7-8) have been maintained. The prior art rejection (item 5) has been obviated. Upon further review of the case, it is deemed necessary to raise new issues that need further rejection.

Election/Restriction

3. Applicant's election of a single species: 2-[2-(3-Amino-piperidin-1-yl)-6-fluoro-4-oxo-4H-quinazolin-3-ylmethyl]-benzonitrile (Example 6 disclosed at page 115 of the specification) filed 4/13/2006 is acknowledged. Applicants traverse the restriction requirement and did not amend the claims as suggested in the previous Office Action. Applicants argue, "The present claims are drawn to a single invention and restriction, to the extent that it is applicable at all, should be based only on a restriction as to species...In this regard, claim 1 is a genus claim (i.e. generic) that links the species claims act to prevent restriction between inventions, even when the inventions would otherwise be divisible. MPEP 809.03. Accordingly, claim 1 is a linking claim that should be examined with the invention elected, and if allowable, the restriction requirement

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should be withdrawn. MPEP 809". The examiner disagrees with applicants.

Applicants have elected a species and the examiner searched the invention by expanding the variables around the elected species. The search was stopped when the examiner found a prior art.

As it was discussed with Mr. David Weitz on 4/27/2006, the nature of the invention is very broad (see for example restriction requirement of a related case 10/809,637). It is recommended that applicants define the variables R_1 and R_2 as discussed during the telephonic interview (4/27/2006).

Claims 34-35, 37-41, 44-54, 62-86, 89-94, 96-98, 101-102 and 104-114 are drawn to non-quinazoline compounds, stand withdrawn from further consideration as not being readable on the elected species.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 8/16/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 11-12, 14, 24, 32-33, 42-43, 55-56 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnickel et al. WO 01/23364 A1. Cited reference at page 1 discloses quinazoline derivatives that are the same as applicants. Specifically, cited reference at pages 49-50 teaches 5 compounds: 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-chloro-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-methyl-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-7-chloro-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-methoxy-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-3H-quinazoline-4-one that are the same as applicants when applicant's Formula XIX have the following substituents: Q = CO; R₁ = substituted cyclohexylmethyl (i.e. Z = CH₂ and R_m = cyclohexyl substituted by aminomethyl); R₃ and R₄ = benzo or chloro- or methoxy-substituted benzo; and R₂ = -CH=CH-4-dimethylaminophenyl (the N atom is separated by 6-atoms from the vinyl linker). The examiner has attached STN printout that shows these 5 compounds.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term "substituted" is indefinite. In the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

Response to arguments

Applicant's argument filed 08/16/2006 has been fully considered but it is not persuasive.

Applicants argue by reciting *Ex parte Lani S. Kangas*, *Mieczyslaw H. Mazurek*, *Kurt C. Melancom*, *Valter R. Romanko*, and *Audrey A. Sherman*, Appeal No. 2002-0250 (BPAI 2002). Applicants also argue by providing the definition of "substituent" from a literature and pointing out the guidance at paragraph [0098] in the specification. In regard to the appeal, every case is judged on its own merit. Since the cases are different one from the other, it is irrelevant to relate a board decision in SN 08/930,771.

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Note that a disclosure in SN 08/930,771 could have been self-explanatory. This is not the situation with the instant case. The specification paragraph [0098] is not limited to the examples given in said paragraph. It is also noted that some of the examples disclosed in the specification for the term "substituent" are not in fact substituents e.g. ester, ketone, aldehyde, etc. It is recommended that applicants recite specific substituents from paragraph [0098] e.g. alkyl, oxo, etc. into the claims to overcome this rejection.

b. In claim 1 or elsewhere in the claims, the phrase "U is a moiety" is indefinite. What is covered by U and what is not?

Response to arguments

Applicant's argument filed 08/16/2006 has been fully considered but it is not persuasive.

Applicants argue that "those skilled in the art would readily understand that U is a 'linker' that joins V to the ring carbon of the compound of Formula XIX. As such, the atoms in the direct chain of atoms that link V to the ring are the atoms that provide the separation between V and the ring. Furthermore, Applicants provide ample descriptions of what may be used as V". The examiner disagrees with applicant's argument. Applicants are silent in answering simple questions raised in previous Office Action. What is covered and what is not? Applicant's argument "what may be used as V" indicates applicants don't have a complete list of said linkers. It appears that applicants

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are claiming "any linker that works". Note that the definition of R₂ remains vague and indefinite.

c. In claim 1 or elsewhere in the claims, the term "comprising" is an open-ended language. It is recommended that applicants delete said term from the claims.

Response to arguments

Applicant's argument filed 08/16/2006 has been fully considered but it is not persuasive.

Applicants argue, "the term 'comprising' is open-ended. However, Applicants are not aware of any provisions in the patent laws that renders the term "comprising" indefinite when used as a transitional phrase in a claim". The examiner disagrees with applicant's argument. All terms that raise the issue of indefiniteness are not necessarily present in the patent laws. In regard to applicant's argument "the MPEP and patent case law recognize that 'comprising' is a term used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.....". The examiner agrees with applicants. Note that the term "comprising" is not an open-ended language when it is used in composition, processes and method of use claims. In compound claims, "comprising" is an open-ended language. For example, V comprises a basic nitrogen atom remains indefinite since it is unclear what other atoms or compounds are present

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beside the basic nitrogen atom. Note that in composition claims or method of use claims, the compounds are well defined and are essential for the invention.

d. In claim 1 or elsewhere in the claim, the phrase "V comprises a basic nitrogen atom that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein" is not clear. Is the ring nitrogen capable of interacting with carboxylic acid or the substituent on the ring is capable of interacting with carboxylic acid? The term "comprises" is also an open-ended language.

Response to arguments

Applicant's argument filed 08/16/2006 has been fully considered but it is not persuasive.

See the above arguments. It is recommended that applicants recite V and delete the functional language "that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein".

e. In claim 1, the phrase "R₃ and R₄ are taken together to form...5 or 6-membered ring" is indefinite. What is the nature of the ring? What is covered and what is not? It is recommended that applicants amend the claim as "R₃ and R₄ are taken together to form...a benzo ring".

Response to arguments

Applicant's argument filed 08/16/2006 has been fully considered but it is not persuasive.

Applicants argue by providing a dictionary that defines "ring", but this is not sufficient to overcome the rejection. The issue is not whether the term "ring" is not clear, but whether the term "ring" is indefinite or not. Applicants are silent to answer simple questions raised in previous Office Action. What is covered by ring what is not? Is a polymer compound with a ring included or not? Is it heterocyclic ring? Is it heteroaryl ring? Bicyclic ring? Tricyclic ring? Polycyclic? Aromatic ring? Fused ring? Spiro ring? Note that "ring" literally covers any compound with a cyclic nature. There is no guidance in the specification that enables one skilled in the art to understand what the term "ring" encompasses. It is recommended that applicants clearly define the term "ring" to overcome this rejection. Note that a "ring" without heteroatom, size or nature of the ring is indefinite.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is

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significant overlap between the instant claims and claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9:00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

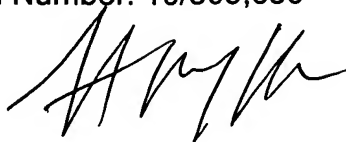
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kahsay Habte
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned to the right of the text 'Art Unit: 1624' and above the text 'Kahsay Habte Primary Examiner Art Unit 1624'.

August 30, 2006